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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/459, 171 12/10/99 ROMANCYK

L 5677-085

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EXAMINER

SOLILA, T

ART UNIT

PAPER NUMBER

1626

DATE MAILED:

10/10/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. 09/459,171	Applicant(s) Romanczyk et al.
Examiner Taofiq A. Solola	Art Unit 1626



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Sep 13, 2001.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 34-119 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 34-119 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10

20)  Other: \_\_\_\_\_

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Claims 34-119 are pending in this application.

Claims 1-33 are canceled.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-119 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The subject matter of the claims are not disclosed in the specification as originally filed. For example, there is no support for the terms "aspirin, heart attack, stroke, hypertension, etc. Therefore, claims 34-119 constitute new matter and must be withdrawn.

The phraseologies "preventing conditions associated with inflammatory diseases," line 1, claims 102, and "preventing conditions associated with inflammation" line 1, claim 111, are not defined in the specification so as to determine the diseases that are embraced by the phraseologies. The claims are drawn to methods of preventing diseases. However, not all diseases caused by inflammatory ~~diseases~~ are preventable. Therefore, the specific diseases must be disclosed in the specification so as to enable the Examiner to determine if such diseases are in

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fact preventable. By including a list of the specific diseases the rejection would be overcome. However, applicants should note that the introduction of new subject matter into the specification will raise the issue of new matter.

The term "food science carrier" in claims 39, 49, 59, 66, 73, 86, 98, 107 is not defined in the specification so as to ascertain what applicants intend to claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34, 44, 54, 61, 68, are drawn to compositions. However, a composition must comprise of more than one component. Otherwise, it would constitute a compound. Therefore, claims 34-36, 44-46, 54-56, 61-63, 68-70, are indefinite. By adding a pharmaceutically acceptable carrier the rejection would be overcome.

The term "food science carrier" in claims 39, 49, 59, 66, 73, 86, 98, 107 is not defined in the claims so as to ascertain what applicants intend to claim. Therefore, claims are indefinite.

The phraseologies "preventing conditions associated with inflammatory diseases," line 1, claims 102, and "preventing conditions associated with inflammation" line 1, claim 111, are not defined in the claims so as to determine the diseases that are embraced by the phraseologies.

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Therefore, claims 102-117 are indefinite. The claims are drawn to methods of preventing diseases. However, not all inflammatory diseases are preventable. Therefore, the specific diseases must be listed in the claims so as enable the Examiner to determine if such diseases are in fact preventable. By including a list of the specific diseases the rejection would be overcome. Applicants are reminded that a claim must stand alone to define the invention, and incorporation into the claim by express reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). See the Examiner's suggestion above.

The phraseologies "modulating nitric oxide," line 1, claim 79; "a method of anti-platelet therapy," line 1, claim 93, "inhibiting lipoxygenase activity," line 1, claim 118, are not necessarily treatment methods as they are directed to the treatment of disease(s). Therefore, claims 79-81, 93-101, 118 are indefinite.

Claims 80, 83-86, 88-92, 94-98, 103-108, 114-117 are improperly dependent on their independent claims for failure to further <sup>limit</sup><sub>their</sub> respectively methods of use.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 34-40, 44-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Clapperton et al., "Polyphenols and Cocoa Flavour", presented at the XVIth Internat. Conference of the Groupe Polyphenols, Lisborn, Portugal, vol. 16, 1992.

Clapperton et al., disclose composition comprising polyphenol (procyanidins) from cocoa. See the summary, page 1, paragraph 2. The procyanidins are in monomers and oligomers (table 1). The compositions are made into liquor (page 2, paragraph 4, line 2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-40, 44-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clapperton et al., "Polyphenols and Cocoa Flavour", presented at the XVIth Internat. Conference of the Groupe Polyphenols, Lisborn, Portugal, vol. 16, 1992.

Applicants claim composition comprising polyphenol (procyanidins) from cocoa. In preferred embodiment the procyanidins is in dimer or oligomer. The composition are in packages having instruction on methods of use. Clapperton et al., disclose composition comprising polyphenol (procyanidins) from cocoa. See the summary, page 1, paragraph 2. The procyanidins are in monomers and oligomers (table 1). The compositions are made into liquor

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(page 2, paragraph 4, line 2). The difference between the instant invention and that of Clapperton et al. is that applicants claim composition in packages having instruction on methods of use. However, being in packages having instruction on methods of use is not in and of itself patentable over the prior art of Clapperton et al. Having composition in packages with instruction on methods of use is well known in the art. Therefore, one of ordinary skill in the art would have known to package the composition of Claperton et al., with instruction on methods of use at the time the invention was made. The motivation is to make additional composition comprising polyphenol (procyanidins).

This is a RCE of applicant's earlier Application No. 09/459,171. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however,

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event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690. The examiner is on flexible work schedule and is generally out of the office on Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Taofiq A. Solola, Ph.D.

Primary Examiner

Group 1626

September 21, 2001